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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,389	07/20/2002	John Reynolds	P1646USA	7079
32116	7590	02/25/2004	EXAMINER	
WOOD, PHILLIPS, KATZ, CLARK & MORTIMER 500 W. MADISON STREET SUITE 3800 CHICAGO, IL 60661			HELMER, GEORGIA L	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

9-AM

Office Action Summary

Application No.

10/009,389

Applicant(s)

REYNOLDS, JOHN

Examiner

Georgia L. Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/10/03</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Status of the Claims

1. Claims 1-15 are pending and are examined in the instant action.

Information Disclosure Statement

2. Applicant's IDS, forms 1449, filed 10 February 2003 is acknowledged and a signed copy included with the Office Action.

Priority

3. The first paragraph of the specification should indicate that this application is a 371 of PCT/US00/12463 filed 5 May 2000.
4. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows: The first paragraph of the specification does not refer to the provisional application and its date of filing.

Claim Rejections - 35 USC § 112 second paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 9, and all claims dependent thereon,

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- are incomplete method claims because the final step of the method does not produce the desired result, namely transformed Allium species.
- “species” should be deleted because it is a plant or plant tissue which is transformed, not a species.
- “gene” is unclear because a “gene” implies a DNA sequence that exists in nature and includes coding and noncoding regions, as well as all regulatory sequences associated with expression. Since this does not appear to be Applicant’s intention, the language “a DNA of interest” is suggested. Or Applicant may recite the various components of the “gene” desired. All recitations of “gene” are also rejected.
- The recitation of “embryogenic callus material” appears to be redundant. Deleting “material” is suggested.

In claims 5, 6, 12 and 13, “EPSPS” is an abbreviation or an acronym.

The full name should be spelled out at least once, preferably at the first recitation of the abbreviation. This should be followed by the abbreviation in parentheses.

In claim 9 a, “about” is unclear since the metes and bounds of “about” are not apparent.

Correction/clarification is required.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 8 and 15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 8 and 15 are drawn to a transformed *Allium* species transformed by the method of claim 1 and progeny thereof. Since the plants and plant material have not been raised under selective conditions, some of the plant material will not be transgenic, rather it will be wild-type, which is a product of nature. Progeny of wild-type tissue are wild-type. Furthermore, due to Mendelian segregation of the transgene, even some progeny of transformed *Allium* will not retain the transgene. See *American Wood v. Fiber Disintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980),

Claim Rejections - 35 USC § 112 Enablement

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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9. Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the *Wands* factors (MPEP 2164.01(a)).

The breadth of the claims: Applicant claims are drawn to a method for transforming an *Allium* species with a heterologous gene, the method comprising the step of contacting embryogenic callus material from an *Allium* species with a bacterium belonging to the genus *Agrobacterium* which contains a heterologous gene, to *Allium cepa* or *Allium fistulosum*, *Agrobacterium rhizogenes* or *tumefaciens*, a Ti or Ri plasmid, the EPSPS gene or a modified EPSPS gene, to embryogenic callus material derived from immature embryos or flower buds, any *Allium* species transformed by these methods, and the progeny thereof

The enablement issues are: all *Allium* species, all explants and a modified EPSPS gene.

Re: *all Allium species*: Applicant claims all *Allium* species, including onion (*Allium cepa*), garlic, leeks, and chives, which are common vegetable crops containing more than 500 species within the genus *Allium* (Eady, New Zealand J. of Crops and Horticultural Science, 1995, vol 23 No. 3, pages 239-250, see page 239. Applicant's IDS). Applicant provides prophetic examples of

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a method of *Agrobacterium* transformation of *Allium cepa* using embryogenic callus derived from immature embryos or flower buds (specification, p. 9-13). *Allium cepa* is thought to be a recalcitrant plant for transformation and regeneration (Eady, *ibid.* p. 243). While one working example may enable a broader scope, Applicant has not provided a single working example of *Agrobacterium* transformation of *Allium cepa* using embryogenic callus derived from immature embryos or flower buds. Applicant's prophetic examples are detailed but lack any showing of exemplified transgenic *Allium cepa* plant material, plants, or progeny. Applicant does not disclose which tissue sources, in combination with which specific treatment protocol and selection conditions function as desired in the claimed invention. Applicant has provided no guidance on how to predictably eliminate inoperable embodiments from a virtually ad infinitum of possibilities other than by random trial and error, which is excessive experimentation and an undue burden.

Re "all explants": Applicant specifies no specific explant source for the embryogenic callus (claims 1-6). Plant transformation procedures employing plant tissue culture are unpredictable. The state of the art is that "plant transformation is an art because of the unique culture conditions required for each crop species. To accommodate a genotype or species that has not been manipulated in culture previously, one must either adapt an established protocol or create a new one." (Hansen et. al., 1999, *Trends in plant Science*, vol 4, pages 226-231, see page 230). *Agrobacterium*-mediated transformation of monocots is particularly unpredictable. Early attempts largely failed, due to failure to identify

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transformation-competent and regenerable cells (see, e.g., Potrykus, Gene Transfer to Cereals: An Assessment, 1990, Biotechnology, 8(6): 535-542 p. 538, column 2, 3rd full ¶). When success is observed, the transformation appear to be transient only (see, e.g., Narasimhulu et. al., 1996, The Plant Cell, Early transcription of Agrobacterium T-DNA genes in tobacco and maize, vol. 8, p. 874, column 2, top ¶; p. 873, column 2, first full ¶). Applicant does not disclose which tissue sources, in combination with which specific treatment protocol and selection conditions function as desired in the claimed invention. Applicant has provided no guidance on how to predictably eliminate inoperable embodiments from a virtually ad infinitum of possibilities other than by random trial and error, which is excessive experimentation and an undue burden.

Re “modified EPSPS gene” : Applicant discloses a specific “modified” EPSPS gene (specification, p. 11, lines 12-22). Many “modifications” of a gene can be made, including deletions, substitutions, insertions, and changes in codon usage. Since Applicant does not require that the modified gene have function, myriads of different modifications, combinations and permutations of modifications can be made. Applicant has provided no guidance on how to predictably eliminate inoperable embodiments from a virtually ad infinitum of possibilities other than by random trial and error, which is excessive experimentation and an undue burden.

In view of the breadth of the claims (any Allium, any explant, and any modified EPSPS), the nature of the invention, the unpredictability of the art, the

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lack the lack of guidance in the specification, undue trial and error experimentations would be required to enable the invention as commensurate in scope with the claims.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claim ⁵8 ^{and 15 are} rejected under 35 U.S.C. 102(b) as being anticipated by Dommissé, et. al., Onion is a Monocotyledonous Host for Agrobacterium. Plant Science, vol. 69 (1990) pages 249-257; Applicant IDS.

Dommissé et al teach Agrobacterium mediated transformation of Allium cepa bulbs, which Agrobacterium contain opine synthase genes heterologous to Allium. See pages 254-44 and Figure 4.

Accordingly, Dommissé anticipates the claimed invention.

See In re Best, 195 USPQ 430, 433 (CCPA 1977), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

See In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

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Remarks


12. No claims are allowed. Claims 1-7 and 9-1⁴ are deemed free of the prior art, given the failure of the prior art of record to teach or reasonably suggest *Agrobacterium* mediated transformation of *Allium cepa* by contacting embryogenic callus with an *Agrobacterium tumefaciens* comprising a heterologous DNA.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0976. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia L. Helmer
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February 21, 2004



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